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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Friedbert Wechs

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HAMMER & ASSOCIATES, P.C.
3125 SPRINGBANK LANE
SUITE G
CHARLOTTE, NC 28226

EXAMINER

GONZALEZ, MADELINE

ART UNIT

PAPER NUMBER

1797

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/588,695	Applicant(s) WECHS ET AL.	
	Examiner MADELINE GONZALEZ	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 December 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 10-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 18 and 19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/8/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of claims 1-9, 18 and 19 in the reply filed on December 18, 2008 is acknowledged. The traversal is on the ground(s) that the unity of the invention was not previously questioned in the International Examination and the method claims depend from the product claims. This is not found persuasive because the inventions do not relate to a single general inventive concept under PCT Rule 13.1 and under PCT Rule 13.2 they lack the same or corresponding special technical features, as shown by the cited references.

The requirement is still deemed proper and is therefore made FINAL.

Claims 10-17 are withdrawn from further consideration because they are drawn to a non-elected invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 1-9, 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over a combination of Sluma et al. (U.S. 5,290,448) [hereinafter Sluma] and Wenthold et al. (U.S. 5,762,798) [hereinafter Wenthold].

With respect to **claims 1, 8 and 9**, Sluma discloses an asymmetric semipermeable membrane, based on a synthetic first polymer, the membrane including:

- an open-pored, integrally asymmetric structure across its wall (see col. 2, lines 44-56);
- a porous separating layer of thickness 0.1 to 2 μm on its inner surface facing a lumen (see col. 2, lines 57-58); and
- an open-pored supporting layer adjoining the separating layer (see col. 2, lines 44-56), and having an ultrafiltration rate in albumin solution in the range of 25 to 60 $\text{ml}/(\text{h}\cdot\text{m}^2\cdot\text{mmHg})$ (see Example 2);
- wherein, after prior drying, the hollow-fibre membrane has a minimum sieving coefficient for cytochrome c of 0.7 combined with a maximum sieving coefficient for albumin of 0.00 (see Example 2).

Sluma **lacks** the minimum sieving coefficient for cytochrome c of 0.8 or 0.85, and the hollow-fibre membrane in the dry state being free from pore-stabilizing additives in the membrane wall.

With respect to the minimum sieving coefficient for cytochrome c of 0.8 or 0.85, Sluma identifies the sieving coefficient as result effective to variables such as stretching and pull-off rate of the fiber (see col. 4, lines 1-14). It would have been obvious to obtain the specific sieving coefficient range for cytochrome c for the membrane

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disclosed by Sluma since the court have held that “where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation (see *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955)).

With respect to the hollow-fibre membrane in the dry state being free from pore-stabilizing additives in the membrane wall: Wenthold teaches an asymmetric semipermeable hollow fiber membrane incorporating a polyamide so that the membrane immediately wets with aqueous solutions without the use of additives, in order to provide an economical fiber (see col. 6, lines 32-39). Wenthold further teaches a sieving coefficient between 0.65-1.0 for molecules having a molecular weight of 17,000 daltons (MW of cytochrome c is about 12,000 daltons and one of ordinary skill would expect the sieving coefficient of cytochrome c to be close to 1) and a sieving coefficient for albumin of 0.0 (see col. 37, lines 15-26). Wenthold shows very high flux rate for the membrane (see col. 37, lines 18-22). It would have been obvious to provide the membrane disclosed by Sluma with a polymer, such as polyamide, so that the membrane immediately wets with aqueous solutions without the use of additives, in order to provide an economical fiber (see col. 6, lines 32-39).

With respect to **claim 2**, Sluma discloses wherein the membrane also has a hydrophilic second polymer (see col. 2, lines 44-48).

With respect to **claim 3**, Sluma discloses the synthetic first polymer is a hydrophobic first polymer and the hollow-fibre membrane also includes a hydrophilic second polymer (see col. 2, lines 44-48).

With respect to **claim 4**, Sluma discloses wherein the hydrophobic first polymer is a copolymer (see col. 2, lines 44-48). Wenthold discloses wherein the hydrophobic first polymer is a polyamide (see col. 6, lines 32-39).

With respect to **claim 5**, Wenthold discloses wherein the hydrophilic first polymer is a polysulfone or a polyethersulfone (see col. 5, lines 12-15).

With respect to **claim 6**, Wenthold discloses wherein the hydrophilic second polymer is polyvinylpyrrolidone (see col. 5, lines 12-15).

With respect to **claim 7**, Sluma discloses wherein the supporting layer extends from the separating layer across essentially the entire wall of the hollow-fibre membrane, has a sponge-like structure and is free from finger pores (see col. 2, lines 44-56).

With respect to **claim 18**, Sluma discloses wherein a polyelectrolyte with negative fixed charges is physically bound in the separating layer (see col. 2, lines 62-64).

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With respect to **claim 19**, Sluma discloses an ultrafiltration rate in albumin solution in the range of 25-60 ml/h m² mmHg. Sluma **lacks** an ultrafiltration rate in albumin solution in the range of 30-55 ml/h m² mmHg. Sluma teaches that the ultrafiltration rate is result effective to the pull-off rate (see col. 4, lines 1-68 and col. 5, lines 1-20). It would have been obvious to obtain the specific ultrafiltration rate for the membrane disclosed by Sluma since the court have held that “where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation (see *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955)).

Double Patenting

Claims 1-9, 18 and 19 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 of copending Application No. 10/588,696. Although the conflicting claims are not identical, they are not patentably distinct from each other. The instant claim 1 has an ultrafiltration rate in albumin solution in the range of 25 to 60 ml/(h m² mmHg), whereas the copending claim 1 has an ultrafiltration rate in the range of 5 to 23.5 ml/(h m² mmHg). However, it appears that the apparatus in the instant claims would function at a lower ultrafiltration rate as there is no structural difference between the membranes. The sieving coefficient of cytochrome c in the copending claim 1 is expressed by a relation, whereas the instant claim discloses the sieving coefficient of cytochrome c as a

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minimum of 0.8. Using the ultrafiltration rate range disclosed by the instant claim 1, the relation disclosed by the copending claim 1 was satisfied in that it is higher 0.8. As further evidence that the copending and instant claims overlap in scope, and therefore are not patentably distinguishable, the copending specification discloses that the minimum sieving coefficient for cytochrome c is preferably 0.8 (Page 11, Lines 1-2). Therefore the sieving coefficient disclosed by the instant application claim 1 are within range of the relation disclosed in the copending claim 1. Instant claims 2-9 and 18 are are identical to copending claims 3-10.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MADELINE GONZALEZ whose telephone number is (571)272-5502. The examiner can normally be reached on M, T, Th, F- 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Duane Smith can be reached on 571-272-1166. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Madeline Gonzalez
Patent Examiner
March 26, 2009

/Krishnan S Menon/

Primary Examiner, Art Unit 1797